STATE OF SOUTH CAROLINA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEDICAID 1115 RESEARCH AND DEMONSTRATION WAIVER APPLICATION:

A PRESCRIPTION DRUG BENEFIT FOR SOUTH CAROLINA'S LOW-INCOME SENIORS

JANUARY 8, 2002

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I. Executive Summary

The State of South Carolina Department of Health and Human Services proposes to provide comprehensive pharmacy benefits and medical case management to low income seniors. Under this program, seniors at or below 200 percent of the Federal Poverty Level will receive a pharmacy benefit under the State's Medicaid program through a Section 1115 Research and Demonstration waiver. Individuals eligible for this waiver program are not eligible for benefits under the current Medicaid rules.

South Carolina has recently made significant efforts to provide a pharmacy benefit to low income seniors under its state funded SilverCard program. However, the current benefit through the SilverCard program is restricted to persons at or below 175 percent of the Federal Poverty Level. Providing an enhanced pharmacy benefit under the proposed waiver will make the benefit available to a greater portion of the elderly population. It will also introduce a comprehensive pharmacy management component to patient care. This combination of benefits should divert seniors from the regular Medicaid program. It is anticipated the program will serve approximately 50,000 of South Carolina's low income seniors in year one to a total of 73,000 by year five of the waiver.

Research has demonstrated that prescription drugs are cost-effective, as compared to hospitalization and nursing home utilization. For example, studies have estimated that every dollar spent on pharmaceutical coverage is associated with a significant reduction in hospital care expenditures. These savings relate not only to the preventive nature of some pharmaceuticals, but also to the fact that coverage gaps cause millions of low-income seniors to reduce their use of clinically essential medications. The improper use of essential medications due to income constraints increases hospital and nursing home admissions, costing more to the health care system in the aggregate.

Undoubtedly, the lack of drug coverage for seniors under the Medicare program is one of today's most important public policy issues. While there has been much discussion regarding this most significant issue, reform on a national level has been slow. South Carolina's proposed waiver, therefore, is a timely program that will fill this gap now and serve as an experiment that tests the cost-effectiveness of pharmaceutical drugs until there is a national solution.

II. Overview

The lack of access to prescription drugs for the elderly is one of the most significant issues facing our national health care system. Numerous studies by Congress, AARP, Families USA and other groups have documented the usage, costs and implications of non-compliance by seniors. In 1999, the Governor's Office in South Carolina sponsored a series of 13 public forums to gather information on the needs of seniors. Over 3,200 persons attended these hearing and the number one topic brought up was the cost of prescription drugs. Many persons told of experiences where they had to choose between food, utilities and other necessities and prescription drugs. Many had prescription drug bills which were five hundred to a thousand dollars a month, leaving little left over for essential items. This situation worsens each day and prescription drugs increase in cost by an average of 20 percent a year.

The State of South Carolina is one of 31 states that has instituted a pharmacy assistance program for low income seniors. In 2000, some 33,500 eligible seniors began receiving benefits under the state funded SilverCard program. This program is currently available to seniors at or under 175 per cent of the Federal Poverty Level (FPL) and do not qualify for Medicaid.

The South Carolina Department of Health and Human Services (the Department), the state agency that administers the Medicaid program, proposes offering an expanded, much more comprehensive pharmacy benefit to seniors 65 and older whose income is at or below 200 percent of the FPL through a Section 1115 Research and Demonstration waiver. Under this proposal, individuals will qualify for pharmacy benefits, including pharmacy case management, The South Carolina Department of Health and Human Services (the Department), the state through the Medicaid program. As a result of the expanded pharmacy benefit, the number of participants in the program will significantly increase. It is anticipated that this proposal will provide access to pharmaceuticals to approximately 50,000 South Carolina seniors.

The prescription drug benefit will be the same as that provided under the State's current Medicaid State Plan, which covers all products that are required under the Omnibus Budget Reconciliation Act of 1990. This comprehensive pharmaceutical benefit package covers all disease states.

By expanding access to prescription drugs for the elderly, South Carolina intends to bridge the gap until a national reform of Medicare prescription drugs can be implemented.

The Department proposes to demonstrate that providing expanded pharmacy benefits to an expanded population will provide the following benefits:

Help to preserve the health of the senior population by providing financial support for costly but essential drugs.

- Improve the quality of life of South Carolina's seniors, thereby allowing them to remain in less costly home settings and avoid expensive acute or long-term care services resulting from a lack of access to necessary drugs.

- Reduce the speed at which seniors "spend down" and become entitled to all benefits available under the Medicaid program.

- Reduce potential Medicaid expenditures for the dual-eligible population.

- Save the federal government money by improving the health of seniors, resulting in savings to the Medicare program.

- Divert Medicare beneficiaries from the Medicaid program.

- Provide a pharmacy case management benefit to assure correct use of medications.

A. History of Pharmacy Programs in South Carolina

The South Carolina SilverCard program was created by permanent budget proviso in 1999. The program is open to all persons who are residents of the state that are 65 years old and over and who have income of 175 percent or less of the Federal Poverty Level. For 2001 that income limit is between $8,591 and $15,032 for a single member household and between $11,611 and $20,317 for a two member household. Additionally the recipient can not have any other prescription drug insurance. Should CMS wish to examine the six month record of the SilverCard program, an independent report is available.

In the first year of operation the SilverCard program has had 33,500 participants. There is a $500 deductible which is paid by each member. During this deductible period the member pays the same price as reimbursed by Medicaid for the drug. After the $500 is met the member pays a $10 copay for generic drugs and a $21 copay for brand name drugs. There is no ceiling or cost limit.

The South Carolina Budget and Control Board, Office of Insurance Services is responsible for the administration of the SilverCard program. They have contracted with a private vendor, Consultec, to perform the day to day activities of the program. Funding for the SilverCard program has been provided entirely by the state from a trust fund containing tobacco settlement funds. The amount appropriated for operations during Fiscal Year 2001 were $20 million. For Fiscal Year 2002 this amount will grow to $24 million.

B. Medicaid Pharmacy Benefits

Currently, the South Carolina Medicaid program coverage for pharmacy benefits is limited to a four prescription limit for adults. This can be over-ridden for medications deemed essential. There is a 34 day supply limit.

C. Prescription Drugs and the Elderly

According to a July 2000 report by the advocacy group, Families USA, entitled "Growth in Drug Spending for the Elderly, 1992 – 2010":

- Although seniors constitute only 13% of the nation's population, they account for 34% of all prescriptions filled and 42 cents of every dollar spent on prescription drugs.

- The average annual spending per elderly person for prescription drugs grew from $559 in 1992 to $1,205 in 2000, an increase of 116 percent.

- By 2010, average spending per person on drugs for the elderly is projected to reach $2,810 a year, an increase of 133 per cent over spending in 2000.

- Spending on prescription drugs by the elderly grew from $18.5 billion in 1992 to $42.9 billion in 2000 and are projected to reach $113.6 billion in 2010.

- The average number of prescriptions taken by seniors continues to increase from 19.6 per elderly person in 1992 to 28.5 in 2000 to a projected 38.5 in 2010 – a 96% increase.

- The average cost per prescription for the elderly increased from $28.50 in 1992 to $42.30 in 2000 to a projected $72.94 in 2010 – a 156% increase.

- In 1996, South Carolina Medicare beneficiaries spend, on average, $499 or 31.3% of their out-of-pocket health care expenditures on prescription drugs. The national average for that same year was $364 or 18% of the national out-of-pocket expenditures.

- In 1996, the average South Carolina senior used $848 worth of prescription drugs. The $499 out-of-pocket spending represents 58.9% of the total cost of drugs.

- Nearly half, 47% of Medicare beneficiaries lack prescription drug insurance coverage all or part of the year.

III. Proposed Pharmacy Waiver Program Design

A. Eligibility Requirements

State Medicaid programs may have two types of eligibility categories: categorically needy and medically needy. Both categories are established under the Social Security Act. Certain groups, such as pregnant women or the elderly, are considered categorically eligible if they also meet income criteria based on the FPL. "Medically needy" eligibles are those that would be categorically needy except for their slightly higher income and resources but who cannot afford to pay their medical bills.

For the purposes of this waiver program, all individuals will be considered categorically needy and eligible for prescription drug services.

To be eligible for prescription drug services under this 1115 Research and Demonstration waiver program, individuals must:

- Meet existing Medicaid residency requirements;
- Meet existing Medicaid rules on citizenship and immigration status;
- Meet existing Medicaid rules regarding inmates and residents of public institutions;
- Be age 65 or older, regardless of Medicare status;
- Have a household gross income at or below 200 percent of the FPL, using existing Medicaid rules for counting income; and
- Have no prescription drug private insurance.
- Individuals cannot spend down to become eligible for the waiver program.

There will be no asset test related to eligibility for the waiver program and there will be no estate claims for services provided under this waiver.

B. Application Process for Pharmacy Waiver Benefits

The application process for eligibles in this 1115 Research and Demonstration waiver program will be comprised of the following components:

- A separate application will be developed for the waiver program; this application will be for the waiver program only.
- South Carolina Medicaid will not review waiver program applications for eligibility for any other Medicaid programs. The application will contain a statement advising

applicants that individuals should complete a full Medicaid application if they are interested in any other benefits.

- Applications will be processed by a central unit. South Carolina maintain the option of using an outside contractor to process applications to determine eligibility.

- Applications will be accepted in person, by mail and, electronically, over the Internet.

- Near the end of an individual's eligibility, the Department will send a renewal application. To continue coverage, the renewal application must be filed in a timely manner and receive approval.

- Upon enrollment, waiver program recipients will receive an identification card distinct from a normal Medicaid card. This card will be replaced biannually when the individual renews enrollment in the program. Recipients must present the identification card at the pharmacy when purchasing prescription drugs.

Because the eligibility requirements for the proposed 1115 Research and Demonstration waiver program are essentially the same as those for the current state-only Pharmaceutical Assistance Program, the Department plans to automatically enroll all individuals in the Pharmaceutical Assistance Program who are 65 and older in the waiver program. These individuals will not be required to submit a new application until their existing enrollment period expires.

C. Enrollment Periods

Enrollment periods for eligibles will be as follows:

- Once determined eligible for the waiver program, an individual will remain eligible for 24 months from the date of initial eligibility, regardless of changes in income.

- Eligibility for benefits will be prospective only; there will be no retroactive eligibility.

- For eligibility determinations made prior to the fifteenth day of a month, eligibility will begin on the first day of the following month. For eligibility determinations made after the fifteenth day of a month, eligibility will begin on the first day of the second month following the month in which the determination was made. (For example, for an eligibility determination made January 10, program eligibility will begin February 1; for an eligibility determination made January 20, program eligibility will begin March 1.)

D. Enrollment Caps

The Department anticipates that the waiver program, when fully implemented, will serve approximately 50,000 individuals in year one and grow to 73,000 by year five. Cost neutrality for the waiver program is predicated on this number of participants. Should the program prove to be such a success that this enrollment number is greatly exceeded, or if the average cost per

individual is significantly greater than originally anticipated, the program will be under-funded at the state level and the Department will be unable to demonstrate cost neutrality. Therefore, to protect the Department from an unforeseen spiraling of program costs, we request that program participation be capped at 50,000. Should waiver program costs prove to be lower than originally estimated, the Department may choose not to implement this cap. South Carolina will inform CMS of any planned changes in this area.

E. Benefits

The waiver program pharmacy benefit will be as comprehensive as that provided in the current South Carolina Medicaid State Plan, which covers all products that are required under the Omnibus Budget Reconciliation Act of 1990 and all disease states, including over-the-counter drugs with a doctor's order. In addition, South Carolina has provided for and additional $64.50 annual payment which would be used for pharmacy case management. This is the equivalent of three physician visits at the current reimbursement rate of $21.50 per visit or six pharmacists consults at a reimbursement rate of $10.75 per consult. The purpose of this patient education and pharmacy case management component is to ensure the member is taking the appropriate amount and types of medications, avoid inappropriate mixing of prescription drugs and/or over-the-counter medications, monitoring of patients for adverse reactions and obtain general preventive medical advice.

F. Cost Sharing

Participants in this program will share the costs of waiver program benefits. Cost sharing will include deductibles and copayments. The following describes the initial cost sharing features in more detail:

i. Deductibles

- Participants will pay a $500 deductible out of pocket for prescription drugs.
- During this deductible period, participants will pay no more for a drug than the reimbursement rate paid by Medicaid.

ii. Copayments

- After the deductible is satisfied, participants will pay $10 for a generic drug and $21 for a brand name drug.

iii. Future Adjustments to Copayments

The Department proposes that it be granted flexibility under the waiver to modify, within specified limits, cost sharing requirements during the term of the 1115 Research and Demonstration waiver program to control program costs. The Department may institute a copayment structure to create an incentive for providers to prescribe drugs that are medically and economically appropriate. Also, Copayments may be waived or reduced for individuals who purchase their pharmaceuticals through one of the various mail order options.

G. Coordination with Other Medicaid Programs

The following are stipulations regarding coordination between the Medicaid program and the 1115 Research and Demonstration waiver program:

- As discussed previously, the Department will not review waiver program applications for eligibility for other Medicaid programs. The application will contain a statement advising applicants that they should complete a full Medicaid application if they are interested in any other benefits.

- Should an individual's income decrease so that they would be fully Medicaid eligible, that individual would have to submit a complete Medicaid application and be determined eligible through existing procedures if they wanted full Medicaid benefits.

- Individuals cannot spend down to become eligible for the waiver program.

- Individuals who are terminated from the waiver program or who fail to re-enroll will not be reviewed for eligibility for other Medicaid programs prior to termination

H. Drug Utilization Review and Case Management

The Department will incorporate into the waiver program various features to enhance the effectiveness of the pharmacy benefit and improve the health of program participants. These may include various drug utilization review (DUR) programs to monitor and evaluate prescriptions to detect inappropriate dosages, drug prescription duplication, drug interaction, prescriptions that are not cost-effective and inadequate therapies.

IV. Waiver Program Implementation and Administration

A. Administering Agency

The Department may administer the waiver program directly or through an interagency agreement with the South Carolina Budget and Control Board. Portions of the program may be administered by a private entity under contract with the State. South Carolina will inform CMS of the final status of the administration mechanism.

B. Financing

Prescription drug and pharmacy case management services under the 1115 Research and Demonstration waiver program will be funded jointly through State funds and matching federal monies.

Additional program revenue for the 1115 Research and Demonstration waiver program will come from the copayment fees mentioned previously and monies from the drug rebate program. South Carolina currently has drug rebate agreements with all pharmaceutical companies participating in the Medicaid rebate program pursuant to Section 1927 of the Social Security Act. This program will continue to rely on these agreements in future periods.

C. Provider Network

The 1,100 Pharmacies currently enrolled in the South Carolina Medicaid program will fill prescriptions for waiver program recipients as well. Access to pharmacies for the waiver program will be readily available as nearly all pharmacies in South Carolina participate in the Medicaid program.

D. Implementation Schedule

The Department expects the waiver program to last for five years and is aggressively pursing an implementation date in 2002. Since many of the program design features are already in place, the Department is confident that the waiver program will be operational by the target date.

E. Early Termination of the Waiver Program

South Carolina reserves the right to end this 1115 Demonstration Waiver should actual experience show that it is not cost effective or cost neutral. Further, South Carolina may amend or terminate this program should a federal program provide access to prescription drugs for all or part of the waiver population. South Carolina residents will not be disadvantaged with regard to their participation in any such federal program as a result of the state's decision to terminate this waiver program. South Carolina may also choose to seek a Medicare waiver for the State in order to coordinate the programs.

V. Waivers Requested

This demonstration program requires waivers from Title XIX of the Social Security Act. Section 1115(a)(1) of the Social Security Act permits South Carolina to waive compliance with any of the requirements of Section 1902 of the Social Security Act, which specify State Medicaid Plan requirements, to the extent and for the period necessary to carry out the demonstration project. Section 1115(a)(2) permits South Carolina to regard as expenditures under the State plan costs of the demonstration project which would not otherwise receive a federal match under section 1903 of the Social Security Act. These provisions allow South Carolina to waive existing program restrictions and provide expanded eligibility and/or services to individuals not otherwise covered by Medicaid. South Carolina seeks to waive the following Title IX provisions:

South Carolina requests that, under the authority of Section 1115(a)(2), expenditures for the items identified below (which are not otherwise included as expenditures under Section 1903) be regarded as expenditures under South Carolina's Medicaid State Plan:

- Expenditures to provide and receive comprehensive pharmacy benefits and pharmacy case management to seniors age 65 and older whose income is at or below 200 percent of the FPL.

- Administrative expenditures for demonstration participants including but not limited to collecting program participants' fees, enrolling pharmacies, producing and distributing enrollment cards to program participants, responding to client inquires, collecting third-party insurance information and evaluation and monitoring of this demonstration waiver.

South Carolina requests the right to consider other waivers to implement the proposed pharmacy program, if necessary.

VI. Program Implications for the Private Health Insurance Industry

Crowd-Out from Expanded Pharmacy Services

Supplemental private insurance, whether former employer-based or individually purchased, is becoming more expensive each year. As a result, the number of seniors with supplemental drug coverage is on the decline. According to a recent *New York Times* article:

"*Fewer employers are offering retiree health coverage, and Medigap is increasingly scarce and expensive.*"[i]

The Current Population Survey indicates that approximately 20 percent of the eligible population for this program may have benefits available to them from employer-sponsored private insurance. South Carolina does not believe that implementation of this program will have a significant impact (crowd-out) on the number of individuals that maintain such insurance.

Because of the income limitation on eligibility for the waiver, it is not expected that many pension plans will be induced to drop pharmaceutical coverage since it would leave all enrollees over 200 percent of the FPL without a viable option for coverage.

It is important to consider that crowd-out strategies could be difficult to administer or difficult to implement given the financial constraints on the program.[ii] It should be emphasized again, however, that South Carolina does not expect the crowd-out phenomenon to occur with the implementation of this proposed waiver program.

VII. Budget and Cost-Effectiveness Analysis

Research shows that appropriate and necessary use of pharmaceuticals improves the health of seniors. Studies have estimated that every dollar spent on pharmaceutical coverage is associated with a $2.10 to $4.00 reduction in hospital care expenditures.[iii,iv,v] For the Medicare program, spending more on prescription drug coverage could save the Medicare trust funds a great deal more in other coverage areas; for the Medicaid program, savings could be realized as a result of a decrease in the need for hospital, long-term care and other related medical services.

Findings released in 1991 show that a New Hampshire policy limiting the number of prescription drugs to seniors resulted in significant cost increases to its Medicaid program.[vi] Although the cost the state paid for pharmaceuticals dropped 35 percent almost one year after the implementation of the limitation, admissions to nursing homes increased 60 percent. The state also saw increases in hospital stays, visits to community mental health centers and emergency mental health services.[vii, viii] When the limitation was removed, total health care costs dropped and admissions to nursing homes returned to their original level.[ix] A recent study done by Columbia University bears this out. This report, contained in the September/October 2001 issue of Health Affairs determined that taking new drug therapies reduced non-drug expenditures by $71, outweighing the average $18 increase in money spent on those new drugs. With the new drugs the likelihood of hospitalization went down one half of one percent. Given that the average hospital stay costs $8,000, expected hospital costs would decrease by $40 to $50.

The absence of pharmaceutical insurance coverage causes millions of low-income elderly to reduce their use of clinically essential medications. This improper use of essential medications increases hospital and nursing home admissions and results in increased health care system costs in the aggregate.[x] Additionally, pharmaceutical drugs may be the only treatment for an illness where no other treatment exists.

For most people, having to make a decision to purchase food or essential medication is not a common occurrence. But for those elderly who do not qualify for state Medicaid programs and who cannot afford to purchase private insurance for prescription drugs, choosing between food and prescription drugs may not be unusual. Data released in 1999 in the *New England Journal of Medicine* showed that:

"*…among Medicare beneficiaries with incomes less than $10,000 [excluding Medicaid eligibles], almost two-thirds have no drug coverage and purchase only half as much medications as those with employer coverage despite being sicker.*[xi]"

It is hard to quantify how elastic low-income seniors' demand is for prescription drugs, but certainly this research implies that as money becomes tighter, people must choose between the immediate needs of food and housing and the more long-term necessity of medicating a chronic illness; for example, taking a blood pressure medication to prevent the future onset of heart disease.

Improved access to prescription drugs for low-income seniors will benefit both state and federal health programs – Medicare will save from reduced hospitalization rates and Medicaid will

realize savings from reduced rates of increases in hospital, nursing home and other medical services utilization.[xii] Consequently, a national program that divides the costs of coverage between state and federal governments, like Medicaid, could be a rational solution to providing access to prescription drugs for low-income seniors.

The Department has estimated the potential cost savings under this proposed waiver program. Based on preliminary estimates, the Department projects that it will not increase its overall Medicaid expenditures for the Aged population, 65 and older, by expanding the pharmacy program under this proposal. Budget neutrality will be achieved by reducing the rate of increase in the utilization of non-pharmacy related services provided to this population (hospital, nursing facility and other non-pharmacy medical services). The savings realized by reducing the rate of increase in non-pharmacy Medicaid services for this population will offset the costs of expanding the pharmacy benefit under this program.

This preliminary cost effectiveness analysis has been completed by projecting Medicaid expenditures for the Aged population under two separate scenarios. The first scenario, shown in Table 1, projects Medicaid Aged population expenditures, without implementation of the pharmacy waiver. The second scenario, shown in Table 2, projects Medicaid Aged population expenditures, including pharmacy expenditures assuming that the pharmacy waiver program is implemented. The assumptions under each of these scenarios are discussed separately below.

A. Without Implementation of the Pharmacy Waiver Program

Without the pharmacy waiver program, the Department estimates that its expenditures for the Aged population 65 and older during the five-year waiver period (state fiscal years 2003 through 2007) will be approximately $2,765,699,517. Table 1 shows projected Medicaid Aged population expenditures, by year for the waiver period, assuming that the pharmacy waiver is not implemented.

Amounts shown in Table 1 for Aged population expenditures are based on actual state fiscal year (SFY) 2000 average expenditure data for all services provided to the Aged population. Average numbers of individuals served were increased from SFY 2000 at a rate of 3 percent per year, which reflects historical average annual increases. Annual expenditures were increased from SFY 2000 at a rate of 12.5 percent per year, also based on historical increases along with projected population increases..

B. With Implementation of the Pharmacy Waiver Program

The analysis of expenditures with the waiver program includes two components. First, Aged population expenditures were projected taking into consideration reduced Medicaid utilization resulting from anticipated diverted eligibles. Second, expenditures under the pharmacy program were estimated. Both of these components are discussed separately.

i. *Projected Aged Population Expenditures with Implementation of the Waiver Program*

With implementation of the pharmacy waiver, the Department estimates that it will be able to divert approximately 4,100 Aged eligibles each year from the Medicaid program. This estimate is based on the assumption that providing pharmacy benefits will prevent catastrophic illnesses requiring institutionalization of persons aged 65 and older, and that those individuals will become Medicaid eligible less quickly. It also assumes that those individuals not necessarily at risk of institutionalization will also maintain their own financial resources for a longer period of time, making them eligible for Medicaid benefits less quickly. With this reduction in Medicaid utilization for the Aged population, the Department projects total Medicaid expenditures for the Aged population will be approximately $2,765,524,527 over the waiver period. This is a cumulative reduction of $174,990 over the waiver period.

Table 2 shows the calculation of Medicaid expenditures for the Aged population taking into consideration the diversion of individuals, but using the same rate of increase assumptions used in Table 1.

ii. *Projected Pharmacy Expenditures Under the Pharmacy Waiver Program*

The Department has projected that, when fully implemented under this proposed waiver, these pharmacy benefits will be provided to approximately 50,000 seniors in year one of the waiver, increasing to 73,000 by year five.

The Department estimates that net pharmacy expenditures will be approximately $6,505 per year for these individuals in the first year of the waiver period, increasing to $10,420 per individual per year by the fifth year of the waiver period. These amounts are based on actual gross pharmacy and case management expenditures of $6,505 for SFY 2000, inflated at a rate of 12.5% through the end of the waiver period. Gross expenditure amounts are adjusted to take into consideration the following projected cost sharing amounts and other reductions:

- Copayments of $10 and $21, respectively, per prescription.
- Reduction in the over-utilization of drugs and choice of less costly drugs because of cost sharing requirements.
- Adjustment to the costs paid by the Department resulting from cost sharing.

It is assumed that enrollment in the pharmacy program will occur over a four year period, with approximately 50,000 enrollees in the first year, increasing ratably to approximately 73,000 by the fifth year.

C. Summary of Cost-Effectiveness

With the pharmacy waiver, total combined expenditures for the Aged population and the expanded pharmacy population will not exceed what expenditures would be for the Aged population without the expanded pharmacy benefit. This expenditure offset will be accomplished by reducing the rate of growth in the Aged population for the waiver period, as a

result of improved health of this population, and by a reduction in the number of individuals in this population that spend down to Medicaid eligibility.

However, an additional and significant benefit of this waiver program, not accounted for in the attached cost effectiveness analyses, is the reduction in expenditures to be realized by the Medicare Program. Similar to savings to be realized by the Medicaid program, it is anticipated that the Medicare program will achieve significant savings through reduced hospitalizations for this population group.

VIII. Program Evaluation and Monitoring

Approximately 91,000 individuals age 65 and over are in the South Carolina Medicaid program in a given year. Of these, nearly 16,000 individuals in this demographic grouping are residents of a nursing facility every year. In total, individuals age 65 and over account for 31,450 general hospital inpatient days, as well as 3.9 million days in long-term care facilities.

The Department believes that by providing access to prescription drugs for this waiver population, these individuals will remain healthier and thus delay their eventual enrollment in Medicaid. As will be discussed in more detail below, using the current data as a baseline, the Department will partially measure the effectiveness of this waiver by the overall decrease in Medicaid hospital and long-term care stays. However, measuring the overall change in Medicaid usage will only partially demonstrate the effectiveness of this waiver as such a limited look would completely ignore resultant Medicare utilization reductions. This beneficial effect to Medicare must also be examined to completely evaluate this waiver.

Therefore, the Department further proposes to obtain Medicare current utilization data to use as a baseline, and subsequent data with which to measure cost-effectiveness. As this is data not readily available, the Department may need to partner with CMS to obtain this data on an ongoing basis. The Department believes that measuring the effect on Medicare is vital to demonstrating program effectiveness since much of this population will never become Medicaid eligible. In short, ignoring Medicare and measuring only resultant Medicaid changes will distort the evaluation process.

In sum, South Carolina's proposed waiver program offers CMS the opportunity to evaluate the cost-savings for both Medicare and Medicaid, and could serve as a model for a future national drug benefit for seniors. Therefore, extensive quantitative and qualitative monitoring is warranted to identify the outcomes and implications associated with its implementation. South Carolina will address the outcomes of its program by exploring three principal research questions:

1. *Health*: Does the waiver program, particularly the pharmacy benefit and pharmacy case management, improve the health of the low-income elderly population?

2. *Resources*: Is there a reduction in the utilization of non-pharmacy services for program participants as a result of the increased access to necessary medications?

3. *Health Policy*: Are the cost savings associated with this program sufficient to influence Medicare or Medicaid policy and planning?

The following sections present a framework that may be used by evaluators to analyze the outcomes of this demonstration waiver.

A. Health

Does the waiver program improve the health of the low-income elderly population covered by the waiver?

The waiver population consists of a heterogeneous group of seniors ages 65 and older. Since health is difficult to quantify and generally declines with age, accurate measurement of the health benefits associated with this demonstration project is complicated. The State, however, will use indirect indicators, such as utilization of the pharmacy benefit, and survey research methods to appraise the outcomes associated with this waiver program. The "health" principles for evaluation and their premises are:

1. Prescription drugs are an input to health that the State will be offering to its seniors ages 65 and older whose income is at or below 200 percent of the FPL. The number of seniors ages 65 and older eligible for this prescription benefit will be established. This number will serve as a baseline measure and a benchmark for evaluating the success of the program in reaching and enrolling eligible seniors.

2. Epidemiological data will be used to evaluate health outcomes for the demonstration population. Medicare data will be used to assess the age-adjusted rates of death associated with acute and chronic diseases treatable with medications. The health outcomes of South Carolina residents with the pharmacy benefit will be compared to low-income seniors in other states and the nation to evaluate the program's effect.

3. Utilization rates will indirectly measure the health outcomes of the waiver participants. The basis of this measure is founded on the assumption that health is associated with reduced use of inpatient hospital services, nursing home care and other medical services provided to the Aged population. South Carolina, therefore, will monitor pre- and post- demonstration inpatient hospital, nursing home utilization data and other medical services for this population. Rates will be adjusted for patient mix to more accurately assess outcomes associated with the waiver.

4. The effects of pharmacy case management will be measured by the changes in medications as a result of these visits. This will be accomplished by a random sample of physician and pharmacist case notes.

B. Resources

Is there a reduction in the utilization of non-pharmacy services for program participants as a result of the increased access to necessary medications?

Increasing access to prescription benefits will decrease adverse health outcomes associated with the lack of proper and sufficient medications for this population. Outlays incurred by providing

this benefit, therefore, will be offset by the savings generated from fewer hospital and nursing home stays (and other home health/long-term care services) and a possible decrease in emergency room services associated with improper patterns of medication usage. The "resource" principles for evaluation and their premises are:

C. Health Policy

Are the cost savings associated with this program sufficient to influence Medicare or Medicaid policy and planning?

Many drivers, such as an aging population and research that makes more medications available to treat a broader range of morbidity, have pressured the United States healthcare system to realize the importance of access to pharmaceuticals. As can be seen from research principles and premises previously mentioned, the information gathered during the evaluation process will be useful for future health care policy and planning. Specifically, the "health policy" principles for evaluation and their premises are:

1. The waiver population consists of citizens at the Medicare qualifying age and therefore demonstration outcomes and data will be relevant to the national debate regarding the addition of a Medicare prescription benefit. Cost-effectiveness analysis will yield the value of pharmaceutical interventions for seniors.

2. The state will have improved the health of its low-income citizens and reduced costs associated with providing care to this segment of the population. This will free health care dollars that policy makers may allocate to other areas of health care.

D. Data Sources: The breadth of this Research and Demonstration project's evaluation will require data from numerous sources. The evaluation will begin at the start of the program and the evaluation process will draw on data on services used prior to and throughout the participants' enrollment in the program. Data on services used prior to enrollment in the demonstration program will allow for the formation of baseline measures and benchmarks. Data sources may include:

1. Prescription drugs are a medical expense that will decrease inpatient and outpatient hospitalization rates and nursing home and other long-term care services. Prospectively, South Carolina will collect and compare rates of inpatient and outpatient hospitalizations and nursing home stays between low-income seniors with and without a prescription drug benefit. Savings associated with the conservation of these healthcare resources will be calculated.

2. Proper and sufficient medication routines for some patients with chronic diseases will decrease utilization of emergency room services. Random sampling of demonstration participants' Medicare records will be used to

evaluate the waiver's ability to reduce the use of emergency room services for certain disease categories. Evaluators will compare emergency room utilization rates for participants before and after their enrollment into the program. Data collected throughout the demonstration will be used to compare medical service costs for people with and without a prescription drug benefit.Historically, the average Aged population served by South Carolina Medicaid increased at a rate of 27 percent from 1993-94 to 2000-2001. Trending will monitor the waiver program's ability to maintain or decrease the State's Aged Medicaid enrollment.

1. *Case Study Interviews, Focus Groups and Surveys*: Structured longitudinal interviews and/or surveys could be used to examine changes in health status and utilization of healthcare services. Surveys or interviews and focus groups could also be used to aggregate information pertaining to perceived changes in quality of life and current and historic utilization of pharmaceuticals. Surveyor interview results would be used in conjunction with data obtained from other sources to evaluate the success of this Research and Demonstration project.

2. *Medicare Claims Data*: This data could be used to assist in establishing changes in utilization patterns for demonstration participants enrolled in Medicare. Medicare's comprehensive database could be used to query data for both waiver and non-waiver participants to evaluate utilization patterns and other relevant factors.

3. *Medicaid Claims Data*: Medicaid claims data for program participants will provide information regarding participant's demographics, prescriptions filled, total number of waiver participants and waiver expenditures. This data could be cross-referenced with Medicare data.

4. *Vital Statistics Reports and Census*: Data from entities such as the South Carolina Department of Health and Environmental Control, the Centers for Disease Control and Prevention and the Census Bureau will be used for benchmarking. These data can be used to compare outcomes of program participants, such as standardized mortality ratios, to the state as a whole and to the nation.

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